UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,578	10/26/2001	Jeffrey S. Kiel	KIEL / 02	4696

26875 7590 10/06/2006

WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,578	KIEL ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,31-48 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,31-48 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114. Claims 1-21, 31-48 and 53 are currently pending for prosecution on the merits.

Status of Application

2. The rejection of the claims 1-21, 31-48 and 53 under 35 USC 103(a) as being unpatentable over Gordiziel (US 6287597) in view of Chopdekar et al. (US 5599846) is maintained for the reason of record.

3. The provisional rejection of the claims 1-21, 31-48 and 53 under the judicially created doctrine of double patenting over claims 1-21, 31-48 and 53 of copending Application No.10/645977 is maintained for the reasons of the record.

4. Applicant's amendment requiring "homogenous suspension being in an amount including a plurality of dosage units, the homogenous suspension being homogenous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units" necessitates a new ground of rejection in this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-21, 31-48 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims in this application introduce new limitation into the claimed invention, namely "dosage units". The examiner determines that when all evidences in the original disclosure are considered and carefully reviewed, the newly amended claims fail to find support in the original specification.

There is no express statement about such limitation that can be found in the specification. Thus, the recitation of such limitation introduces new matter. As discussed in preceding comments, the limitation recited in the present claims, which did not appear in the specification filed, introduces new concepts and violate the description requirement of the first paragraph of 35 USC 112.

For the examination purpose, the term "dosage unit" is interpreted as "dosage forms".

6. Claim 1-21, 31-48 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to the "the homogenous suspension being in an amount including a plurality of dosage units present",

Similar to the amendment filed July 22, 2004, the amendment filed July 24, 2006 requires that phenylephreine and pyrilamine as active pharmaceutical ingredients are present as a plurality of dosage forms in the homogenous suspension.

The specification discloses that the pharmaceutical composition of the present invention is prepared in a single dosage form, wherein said single dosage forms include suspension and tablets (page 4, lines 4-9). Reading the entire specification, those skilled in the art would have understood that tannate salts of pyrilamine and phenylephrine is prepared in a single dosage form, not plurality of dosage form. The instantly claimed plurality of dosage forms includes a possibility that each of phenylephrine and pyrilamine is present in different dosage forms, for example phenylephrine in tablet and pyrilamine in suspension respectively. Clearly, there is no support in the specification that said tannate salts of pyrilamine and phenylephrine is being present in multiple dosage forms in said composition.

With the exception of "single dosage form", the skilled artisan cannot envision that tannate salts of phenyephrine and pyrilamine are present in said composition as a plurality of dosage form. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Vas-Cath Inc. Mahurkar, 19 USPQ2d 1111, makes clear the "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966(1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)* ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 31 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 31 and 53 recite "homogenous suspension being in an amount including a plurality of dosage units, the homogenous suspension being homogenous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units ".

It is not clear what is meant by "being in amount including a plurality of dosage units...when compared with each of the other dosage units", and the specification does not define how to ascertain the requisite degree of concentration or amounts of the active ingredients in "dosage units". Furthermore, it is not clear what is being compared with. Applicant is requested to clarify.

When the claimed composition is prepared in a single dosage form, especially in homogenous suspension, each of the active ingredients cannot be existed in a plurality of dosage forms as the claimed invention. Thus, this inconsistency between the disclosure and the claims leads to lack of clarity of the claims as a whole.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-21, 31-48 and 53 is rejected under 35 USC 103(a) as being unpatentable over Gordiziel (US 6287597) in view of Chopdekar et al. (US 5599846).

Gordiziel discloses a composition consisting essentially of phenylephrine tannate and pyrilamine tannate and the unspecified components such as benzoic acid, coloring, natural and artificial flavors, glycerin, kaolin, magnesium aluminum silicate, methyl paraben, pectin, purified water, saccharin, sodium hydroxide and sucrose or sorbitol, wherein said composition is prepared in a conventional manner; and wherein said composition is prepared in various dosage forms including suspension such that each 5ml (one teaspoon) contains 30mg of pyrilamine tannate and 5mg of phenylephrine tannate (column 2, lines 51-64 and Examples 1-2). Gordiziel discloses that beside the conventional isopropanol route, antihistamines in the form of their tannate salts can be prepared alternatively in the water route (column 1, line 60 thru column 2, line 6).

Chopdekar discloses an antihistamine tannates (e.g., phenylephrine, pyrilamine, etc...) prepared by water route. Chopdekar teaches or suggests the advantage of preparing antihistamine tannates in water route compared to the conventional isopropanol route, wherein the water route yields about 90-97% of the tannate salts products and about 90-98% of the product purity

compared to only about 70% of the yields and about 85-90% wt % of the purity in the isopropanol route.

As indicated in preceding statement, both the referenced composition (Gordiziel) and the claimed composition (final composition prepared by the claimed steps) are directed to the same composition. However, the teaching of Gordiziel'597 differs from the claimed invention in (i) the specific step of making said composition by the water route, namely step of conversion of the active pharmaceutical ingredients into tannate salts prepared by reacting phenylephrine and pyrilamine in the form of free base with tannic acid in the presence of water and mixing with the known secondary agents or dispersing agents to derive at the claimed homogenous suspension, homogenous granulation or homogenous composition (being in an amount including a plurality of dosage units, the homogenous suspension, granulation or composition being homogenous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units"), without isolation or purification step; (ii) the specific amounts (or ratios) of active and/or inactive ingredients in a composition; and (iii) the specific pH of the said composition. To incorporate such teaching into the teaching of Gordiziel, would have been obvious in view of Chopdekar who teaches or suggests the advantage of preparing antihistamine tannate in water route.

One having ordinary skill in the art would have been motivated to prepare the claimed composition by the water route such that the yield and the purity of antihistamine (pyrilamine and phenylephirne) tannates would be greatly increased. Although the prior art references in combination do not specifically disclose the claimed order (or step) of preparing said

composition, such determination of order of performing step is prima facie obvious in the absence of new or unexpected results.

The patentability of the product is not dependent upon the manner in which is produced unless the process changes the product. In this situation, both products in the prior art and the instant invention are drawn to the same composition.

With respect to the claimed "homogeneous suspension", since the suspension containing pyrilamine and phenyephrine tannates taught in the USP'597 must be existed in homogenous suspension, the prior art references in combination makes obvious the instant invention.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

In addition, optimization of amounts (or ratios) of known active and inactive ingredients in a composition or determination of optimum pH is well considered within the skill of the artisan, absent evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-21, 31-48 and 53 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-21, 31-48 and 53 of copending Application No.10/645977. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claimed invention overlaps to each other.

The copending application is directed to a composition comprising component A (phenyephrine), component B (pyrilamine) and component C (dextromethorphan) whereas the instant invention is directed to a composition consisting essentially of component A (phenylephrine) and component B (pyrilamine). The selection of the components A and B from composition comprising the components A, B and C to make the composition consisting essentially of the components A and B is considered obvious task for the skilled artisan, in absence evidence to the contrary or showing that the introduction of steps or components would materially change the invention.

Response to Arguments

10. Applicants' arguments filed July 24, 2006 and the resubmitted Declaration filed November 03, 2005 have been fully considered but they are not persuasive.

Applicant's argument in the response takes the similar position to the previous arguments considered (February 23, 2004, July 22, 2004 and November 03, 2005) that the novel proves of using (i) the recited use of a separate dispersion (including a dispersing agent such as magnesium aluminum silicate, xanthan gum and cellulose compounds) prevents the aggregation of the tannate salts as they precipitate out of solution and (ii) by starting with the free base or common salt form of the active ingredient as opposed to the tannate form isolated and then used in the prior art method, the claimed composition exhibits less variability in amounts of active pharmaceutical ingredients. Applicant asserts that the claimed composition prepared by the instant manner enhances uniformity ("homogenous" characteristics) of amount of active ingredient from dosage unit to dosage unit, as opposed to the variable levels of active pharmaceutical ingredients which were present in compositions of the prior art.

Applicant's argument is not found persuasive. As discussed in the previous Office Action mailed 05/04/2005 and 01/24/2006, the patentability of the product is not dependent upon the manner in which is produced unless the process changes the product. In this situation, both products in the prior art and the instant invention are drawn to the same composition. Regardless of the alleged "without isolation or purification" process or the uniformity of the composition or homogenous suspension, granulation or composition from one dosage unit to the next, the instantly claimed composition is obvious over the cited references in combination (Gordiziel and Chopdekar), especially in view of about 90-98% of the product purity prepared by the prior art method (Chopdekar).

As discussed above, although the applicant recites the language of "homogenous suspension", "homogenous granulation" or "homogenous composition" ("being in an amount

including a plurality of dosage units...being homogenous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units"), the underlying meaning of the recited languages are substantially similar to the amendments filed 02/23/04 and 07/22/04 which recited "being present as a plurality of dosage forms, each of said dosage forms including an amount of said active pharmaceutical ingredients, said amount being generally uniform in each of said dosage forms, when compared one to another". Since the arguments presented by the applicant in the Response filed July 24, 2006 are similar to the arguments considered (February 23, 2004, July 22, 2004 and November 03, 2005), the examiner maintains the rejection for the reasons of record.

Applicant's argument in the response takes the position that the claims of copending application 10/546977 recite active pharmaceutical ingredients consisting essentially of phenylephrine, pyrilamine, and dextromethorphan. Applicant asserts that each of the actives recited in the claims of the copending '977 application have a specific purpose (e.g., as an antihistamine, antitussive or decongestant), thus, the removal of any ingredient materially changes the composition in that there is no longer a specific effect of the composition.

This argument is not found persuasive. Unlike the applicant's argument, the interpretation of the instant claims (particularly claims 1, 31 and 53) reciting "a composition comprising..." allows for the inclusion of any other unspecified ingredients even in major amounts in said composition. Thus, the copending application makes obvious the instant invention.

Conclusion

11. No Claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614